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DATE: October 27, 2005

PTO IDENTIFIER: Application Number 10/537,075
Patent Number

Inventor: Maria Keßeler, et al.

MESSAGE TO: USPTO PTAS System

FAX NUMBER: (571) 273-8300

FROM: CONNOLLY BOVE LODGE & HUTZ LLP
Hui-Ju Wu, Ph.D.

PHONE: (302) 658-9141

Attorney Dkt. #: 12810-00091-US

PAGES (Including Cover Sheet): 13

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In re Patent Application of:
Maria Keßler, et al.

Conf. No.: N/A

Application No.: 10/537,075

Group Art Unit: N/A

Filed: June 1, 2005

Examiner: Not Yet Assigned

For: L-RHAMNOSE-INDUCIBLE EXPRESSION
SYSTEMS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**TRANSMITTAL OF TRANSLATION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Dear Sir:

Applicants enclose herewith the Translation of the International Preliminary
Examination Report.

Applicants believe no fee is due with this communication. However, if a fee is
due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted
to be filed or which should have been filed herewith (or with any paper hereafter filed in
this application by this firm) to our Deposit Account No. 03-2775, under Order No.
12810-00091-US, from which the undersigned is authorized to draw.

Dated: August 31, 2005

Respectfully submitted,

By


Hui-Ju Wu, Ph.D.

Registration No.: 57,209

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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU *US-Consul*

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rule 71.2)

To:

BASF AKTIENGESELLSCHAFT
67056 LUDWIGSHAFEN
ALLEMAGNE

Patente, Marken u. Lizenzen

27. Juli 2005

Date of mailing (day/month/year)
21 July 2005 (21.07.2005)

Applicant's or agent's file reference
0000054108

IMPORTANT NOTIFICATION

International application No.
PCT/EP2003/013367 ✓

International filing date (day/month/year)
27 November 2003 (27.11.2003) ✓

Applicant

BASF AKTIENGESELLSCHAFT et al ✓

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, GH, KG, KP, KR, MK, MZ, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, BA, BB, BG, BR, BW, BY, BZ, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, ED, EE, EG, EP,
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YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yolaine Cussac

Facsimile No. +41 22 740 14 35

Facsimile No. +41 22 336 70 80

PCT/EP2003/013367



Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054105	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPHA/416)	
International application No. PCT/EP2003/013367	International filing date (day/month/year) 27 November 2003 (27.11.2003)	Priority date (day/month/year) 02 December 2002 (02.12.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/63		
Applicant BASF AKTIENGESELLSCHAFT		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13 May 2004 (13.05.2004)	Date of completion of this report 24 January 2005 (24.01.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

Form PCT/IPHA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/013367

I. Basis of the report

1. With regard to the elements of the international application^a

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-36 - 1-21, as originally filed
 pages, filed with the demand
 pages, filed with the letter of
- ☒ the claims:
 pages 1-15, as originally filed
 pages, as amended (together with any statement under Article 19), filed with the demand
 pages, filed with the letter of
- ☒ the drawings:
 pages 1, as originally filed
 pages, filed with the demand
 pages, filed with the letter of
- ☐ the sequence listing part of the description:
 pages, as originally filed
 pages, filed with the demand
 pages, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig. _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).^{a*}

^a Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

^{a*} Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/13367

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-15	YES
	Claims		NO
Inventive step (IS)	Claims	1-15	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations

1. Prior art documents D1 to D5 are as cited in the International Search Report (the numbering follows the order in which they are listed).
2. The subject matter of claims 1 to 15 is considered novel and inventive in relation to the searched prior art.

Document D1 describes a prokaryotic expression system that uses the L-rhamnose-inducible $rhaP_{BAD}$ promoter from *E. coli*. It is stated that in *E. coli*, L-rhamnose is actively absorbed into the cells by a transport system (RhaT) and converted by an isomerase (RhaA) into L-rhamnulose, which is then phosphorylated by a kinase (RhaB) (see page 33, column 2). D1 points out that rhamnose is a relatively expensive sugar, and that for this reason the *rhaB* gene that encodes rhamnulose kinase was selectively inactivated, thereby reducing the amount of rhamnose needed for induction. The use of a rhamnose-negative strain, in particular a *rhaB*-negative strain, is recommended, especially for fermentations carried out as fed-batch processes (column 35, column 1). Document D2 also discloses a prokaryotic expression system that uses the

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP 03/13367

L-rhamnose-inducible $\text{rhaP}_{\text{rhaB}}$ promoter and a rhaB -deficient host cell.

The subject matter of claim 1 differs from the above in that a host cell which is deficient in L-rhamnose isomerase is used.

According to the applicant, example 8.2 of the application is evidence that, even in the case of cultivation in a fermenter, if rhamnose isomerase is excluded the added rhamnose is not metabolised, whereas D2 shows (see in particular page 100, left-hand column) that in the case of cultivation in a fermenter with a rhamnose concentration of 0.5 g/l the rhamnose is almost completely absorbed by the cells. This argument is basically tenable.

The problem addressed by the present invention is therefore seen as that of providing an improved method for expressing nucleic acids in prokaryotic host cells using the $\text{rhaP}_{\text{rhaB}}$ promoter.

The solution involving the method according to claim 1 is considered inventive because a person skilled in the art would not expect, in the light of D1 or D2, that excluding the isomerase gene would have advantages over excluding the kinase gene. An inventive step can therefore be acknowledged for claims 1 to 15.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 33 and Rule 70)

Applicant's or agent's file reference 0000064103	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/415)
International application No. PCT/EP 02/19347	International filing date (day/month/year) 27.11.2003	Priority date (day/month/year) 02.12.2002	
International Patent Classification (IPC) or national classification and IPC C12N 15/53			
Applicant BASF AKTIENGESELLSCHAFT et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 33.
2. This REPORT consists of a total of 6 sheets including this coversheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been forwarded and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.15 and Section 007 of Administrative Instructions under the PCT). These annexes consist of a total of sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement according to Article 68.2(a) with regard to novelty, inventive step or industrial applicability; objections and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 13.05.2004	Date of completion of this report 24.01.2005
Name and mailing address of the IPEA/ European Patent Office D-80289 Munich Tel. +49 89 23359-0, Tlx 823689 epma d Fax +49 89 23359-4485	Authorized officer: Glebova, K Telephone No. +49 89 23359-5549

Form PCT/PEA/408 (cover sheet) (January 2004)

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP 03/13387

I. Basis of the report

1. This report has been drawn up on the basis of the following elements (*the replacement sheets received by the receiving office in response to an invitation according to Article 14 are considered in the present report as "originally filed" and are not annexed to the report as they contain no amendments (Rules 70.16 and 70.17).*):

Description, pages:

1-38 as originally filed

The sequence listing part of the description, pages:

1-21 as originally filed

Claims, No.:

1-15 as originally filed

Drawings, sheets:

1 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP 03/13367

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig

5. ☐ This report has been written disregarding (some of) the amendments, which were considered as going beyond the description of the invention, as filed, as is indicated below (Rule 70.2(c)):

(All replacement sheets comprising amendments of this nature should be indicated in point 1 and attached to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	1-15
	No:	Claims	
Inventive Step	Yes:	Claims	1-15
	No:	Claims	
Industrial Applicability	Yes:	Claims	1-15
	No:	Claims	

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY**EXAMINATION REPORT**

International application No. PCT/EP 03/13387

SUPPLEMENTARY SHEET

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The prior-art documents D1 to D6 are hereinbelow numbered as they appear in the international search report.
2. The subject matter of claims 1-15 is considered as novel and inventive in the light of the disclosed prior art.

Document D1 describes a prokaryotic expression system using the L-rhamnose-inducible *rhaP_{BAD}* promoter from *E. coli*. It is detailed that, in *E. coli*, L-rhamnose is taken up into the cells actively via a transport system (RhaT) and converted, using an isomerase (RhaA), into L-rhamnulose which is further phosphorylated by a kinase (RhaB) (page 33, column 2). The document mentions that rhamnose is a relatively expensive sugar, which is why the *rhaB* gene, which codes for rhamnulose kinase, has been inactivated in a targeted fashion, whereby it was possible to reduce the amount of rhamnose required for the induction. The use of a rhamnose-negative strain, in particular of an *rhaB*-negative strain, is recommended especially for fermentations which are carried out as a fed-batch process (page 35, column 1). Document D2, too, discloses a prokaryotic expression system using the L-rhamnose-inducible *rhaP_{BAD}* promoter and an *rhaB*-deficient host cell.

The subject matter of claim 1 differs from the above by the fact that a host cell which is deficient with regard to L-rhamnose isomerase is being used.

The applicant has put forward the opinion that example 8.2 of the application proves that, when rhamnose isomerase is eliminated, the added rhamnose is not metabolized, even in the case of cultivation in the fermenter, whereas it can be seen from D2 (see in particular page 100, left column), that, in the case of cultivation in the fermenter at a rhamnose concentration of 0.5 g/l, virtually all of the rhamnose can be taken up by the cells. In its essence, this argumentation can be followed.

Form PCT/supplementary sheet/409 (sheet 1) (EPC-April 1997)

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
SUPPLEMENTARY SHEET**

International application No. PCT/EP 03/13367

As a consequence, the problem to be solved with the present invention is seen in the provision of improved methods for expressing nucleic acids in prokaryotic host cells using the rhaP_{cap} promoter.

The solution of this problem by providing the method as claimed in claim 1 is considered as inventive because, in the light of D1 or D2, the skilled worker could not have expected that eliminating the isomerase gene would have advantages over eliminating the kinase gene. Thus, inventive step is acknowledged for claims 1-15.

Form PCT/supplementary sheet/405 (sheet 2) (EPO-April 1997)

GESAMT SEITEN 06

PTO/SB/97 (09-04)

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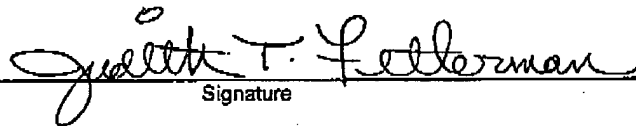
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Application No. (if known): 10/537,075

Attorney Docket No.: 12810-00091-US

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DATE: October 27, 2005

PTO IDENTIFIER: Application Number 10/537,075
Patent Number

Inventor: Maria Keßeler, et al.

MESSAGE TO: USPTO PTAS System

FAX NUMBER: (571) 273-8300

FROM: CONNOLLY BOVE LODGE & HUTZ LLP
Hui-Ju Wu, Ph.D.

PHONE: (302) 658-9141

Attorney Dkt. #: 12810-00091-US

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In re Patent Application of
Maria Keßeler, et al.

Conf. No.: N/A

OCT 27 2005

Application No.: 10/537,075

Group Art Unit: N/A

Filed: June 1, 2005

Examiner: Not Yet Assigned

For: L-RIAMNOSE-INDUCIBLE EXPRESSION
SYSTEMS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**TRANSMITTAL OF TRANSLATION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

Dear Sir:

Applicants enclose herewith the Translation of the International Preliminary
Examination Report.

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due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted
to be filed or which should have been filed herewith (or with any paper hereafter filed in
this application by this firm) to our Deposit Account No. 03-2775, under Order No.
12810-00091-US, from which the undersigned is authorized to draw.

Dated: August 31, 2005

Respectfully submitted,

By Hui-Ju Wu
Hui-Ju Wu, Ph.D.

Registration No.: 57,209
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
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